Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Safety Survey

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)), FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply. FDA is planning to conduct a consumer survey about food safety under this authority. The food safety survey will provide information about consumers' food safety awareness, knowledge, concerns, and practices. A nationally representative sample of 2,000 adults in households with telephones and cooking facilities will be selected at random and interviewed by telephone. Participation will be voluntary. Detailed information will be obtained about risk perception, perceived sources of food contamination, knowledge of particular micro-organisms, safe care label use, food handling practices, consumption of raw foods from animals, information sources, and perceived foodborne illness experience. Most of the questions asked are identical to ones asked in a 1992–1993 survey so that changes over this time period can be assessed.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
2,000	1	2,000	.5	1,000

There are no operating and maintenance costs or capital costs associated with this information collection.

This will be a one-time survey. The burden estimate is based on FDA's experience with the 1992–1993 survey mentioned previously.

Dated: August 6, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–21293 Filed 8–11–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA–225–97–4000]

Memorandum of Understanding Between the Food and Drug Administration and the Department of Defense

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the FDA and the Department of Defense (DoD). The purpose of the MOU is for FDA to provide the quality assurance support for DoD centrally managed contracts for drugs, biologics, and medical devices. This MOU supersedes the agreement concerning drugs and biologics, dated December 17, 1975, and the agreement concerning devices, dated December 23, 1981.

DATES: The agreement became effective January 14, 1997.

FOR FURTHER INFORMATION CONTACT: Paul Donnelly, Medical Products Quality Assurance Staff, Office of Regulatory Affairs (HFC–240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0383.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOU's between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of an MOU.

Dated: August 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

Memorandum of Understanding Quality Assurance Support for Medical Products Between the Department of Defense and the Food and Drug Administration

I. Purpose

To formalize a memorandum of understanding (MOU) between the Department of Defense (DoD) and the Food and Drug Administration (FDA) whereby FDA provides the quality assurance support for DoD centrally managed contracts for drugs, biologics, and medical devices (hereinafter referred to as medical products), as defined by the Federal Food, Drug and Cosmetic Act (FDC Act), as amended, 21 U.S.C. 301 *et seq.* (1972 & Supp. 1979). This agreement supersedes the two currently effective agreements, the drug agreement dated 12/17/75 and the device agreement dated 12/23/81.

II. Background

The Office of Management and Budget (OMB) and the General Accounting Office (GAO) completed separate studies in late 1973 of nonperishable subsistence supplies. Both OMB and GAO recommended that the FDA be the agency responsible for quality assurance of all medical products procured by Federal agencies. In June 1974, the Director of OMB requested that the Department of Health, Education and Welfare (HEW) take the lead in developing an Executive Branch Plan for the government-wide quality assurance program for medical products. FDA was made responsible for developing and implementing the plan. In December 1975, FDA and DoD signed a quality assurance agreement covering drugs and biologics, and in December 1981, a corresponding agreement covering medical devices was signed. Both agreements were implemented and have been operational. However, some portions of the original agreements have become obsolete and there is a need to encompass new DoD initiatives and business practices. This updated memorandum of understanding encompasses all medical products under FDA regulatory control, and supersedes the two currently effective interagency agreements.

III. Responsibilities

A. Under the authority of DoD Directive 4140.26, the Defense Personnel Support Center (DPSC) is assigned and designated as the integrated manager for medical products. The DPSC agrees to:

(1) Furnish FDA copies of medical product quality complaints, incident reports under the Safe Medical Device Act of 1990, and other information which may impact adversely on the quality of a medical product.

(2) Provide a written request for evaluations, testing, and other work to be performed by FDA under this program.

(3) Furnish FDA copies of specifications for review, solicitations and copies of contracts requiring FDA source inspection.

(4) Notify the FDA liaison officer in writing of changes in acquisition regulations and practices which would affect the program covered by this MOU.

B. The Food and Drug Administration (FDA) agrees to:

(1) Furnish DPSC reports of complaint investigations.

(2) Upon request, provide pre-award quality evaluations for firms.

(3) Promptly advise DPSC when firms supplying medical products to DoD become unacceptable from a quality assurance standpoint.

(4) Determine the amount and nature of work it will perform to fulfill its responsibilities under this MOU.

(5) Make available FDA inspectional and analytical personnel as witnesses and supply information and data to DoD for GAO protests, Boards of Contract Appeals, SBA and similar cases.

(6) Review proposed specifications and provide comments on the quality assurance aspects.

(7) Notify the DPSC liaison officer in writing of changes arising from statutes or regulations which would affect this program.

(8) Promptly notify DPSC of product recalls and other pertinent information that affects government contracts or stocks.

(9) Advise DPSC of instances where fraud or other criminal conduct involving government contractors is found.

(10) Be responsible for determining that medical products offered for delivery were produced in accordance with the contract requirements, and for signing the acceptance document when source inspection is required.

(11) Conduct laboratory testing as necessary and, as expeditiously as possible, furnish DPSC analytical results. If testing cannot be accomplished, FDA will notify DPSC.

(12) Advise DPSC when FDA determines that it is necessary to convert a contract from destination to source inspection.

IV. Administration

A. Resources required to support this MOU will be provided by the performing party.

B. Nothing in this MOU will preclude DoD representatives from making visits to suppliers with FDA or separately.

C. The DPSC contracts for medical products will include a provision requiring compliance with the FDC and implementing regulations promulgated thereunder. The Good Manufacturing Practice Regulations will be the quality standard applied to industry for the manufacturing, processing, packaging or holding of medical products acquired on government contracts. The FDA will be the agency responsible for the administrative interpretation and enforcement of these statutes and regulations.

D. The DPSC may authorize the FDA to act as its agent for purposes of inspecting and accepting centrally acquired medical products, performance of preaward surveys, and related quality assurance actions.

E. As a general rule, the quality standards prescribed by the United States Pharmacopeia (USP), the National Formulary (NF), and FDA will satisfy the DoD quality requirements for products covered by the MOU; however, this does not preclude the development and utilization by DoD of additional standards when deemed essential to satisfy a unique or special requirement of DoD or any of the Military Services.

F. The FDA and DPSC, as necessary, will jointly prepare procedures covering operations that interface.

V. Participating Activity Liaison Officers

A. For the Department of Defense: Director, Medical Material, DPSC–M, Defense Personnel Support Center, Defense Logistics Agency, 2800 South 20th Street, Philadelphia, Pennsylvania 19101–8419, 215–737–2100.

B. For the Food and Drug Administration: Director, Medical Products Quality Assurance Staff, HFC–240, Office of Regulatory Affairs, Food and Drug Administration, 12720 Twinbrook Parkway, Bldg. #4, Room 408, Rockville, Maryland 20852, 301–827–0390.

VI. Period of Memorandum of Understanding

a. This MOU will become effective upon final signature and will remain in effect indefinitely.

b. The MOU will be reviewed every two (2) years to ensure adequacy and currency; however, it may be amended by mutual consent at any time.

c. The MOU may be unilaterally terminated by providing the other party with 180 days written notice of intent.

Approved and Accepted for the Department of Defense
By: Edward D. Martin, M.D.
Title: Principal Deputy Assistant Secretary of Defense, Health Affairs
Date: January 14, 1997

Approved and Accepted for the Food and Drug Administration
By: M. A. Friedman
Title: Deputy Commissioner for Operations
Date: November 27, 1996

[FR Doc. 97–21242 Filed 8-11-97; 8:45 am]
BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0302]

Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Consumer-Directed Broadcast Advertisements.'' The draft guidance is intended to provide information to enable product sponsors to fulfill the requirements for consumer-directed broadcast advertisements, while providing consumers with required risk information about the advertised products. This draft guidance represents the agency's current thinking on consumer-directed broadcast advertisements for prescription drugs for humans and animals, and human biological products. The agency requests comments on this draft guidance.

DATES: Written comments may be submitted on the draft guidance document by October 14, 1997. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFD–305), Food and Drug Administration, 12420 Parklawn Dr., rm 1–23, Rockville, MD 20857. Submit written requests for single copies of the draft guidance entitled ''Consumer-Directed Broadcast Advertisements'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT:

Regarding prescription human drugs: Nancy M. Ostrove, Division of Drug Marketing, Advertising and Communications (HFD–40), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, rm. 17B04, Rockville, MD 20857, 301–827–2828, or via e-mail at ostrove@cder.fda.gov.

Regarding prescription human biological products: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–200), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028, or via e-mail at stifano@cber.fda.gov.

Regarding prescription animal drugs: Edward Spenser, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD, 20855, 301–594–1722, or via e-mail at espenser@bangate.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory and Regulatory Requirements

Section 502(n) (21 U.S.C. 352(n)) of the Federal Food, Drug, and Cosmetic